

**Remarks**

Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 1-36 have been cancelled.

**Rejection Under 35 U.S.C. §112**

Claims 37-47, 51-52 and 54-62 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Applicants respectfully disagree.

The Examiner contends that the claim limitation of a specific effect (i.e., an increase peptide load or solubility) is not adequately described by the specification. Because there are uncertainties regarding the exact type of modifications that would yield the specified effect, the Examiner believes that the claims should be limited to the working examples. Furthermore, the Examiner contends that the specification does not show a nexus between a lower isoelectric point and increased peptide load or solubility.

Applicants contend that the specification teaches how to lower the isoelectric point of a peptide and how to conjugate that peptide. The specification shows a number of examples where lowering of the isoelectric point of a varied number of peptides does increase peptide load. Even if some of the peptides with lowered isoelectric points did not have increased load when conjugated to some carriers, the claims are not necessarily invalid. Even though there is uncertainty in practicing the claimed methods, under the applicable case law, ‘It is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ‘ Atlas Power Co. v.

E. I. Du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984) citing In re Dinh-Nguyen, 492 F.2d 856, 858-859, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted).

Furthermore, the nexus of the methods of the invention with the stated effect does not have to be absolute. Just because lowering of the isoelectric point of some peptides in conjunction with some carriers does not increase peptide load, it does not follow that the specification does not adequately describe the present invention. There can be inoperable species. One skilled in the art can take the teachings of the specification and practice the invention.

The Examiner is concerned by the fact that the broadest claims encompass conjugation of any peptide (not restricted to sequence) and any carrier. However, Applicants point out that the isoelectric point of any peptide can be lowered, regardless of its initial sequence. The lowering of the isoelectric point is what allows the peptide to have increased load onto a carrier. Applicants have described a number of ways to accomplish this goal in the specification and therefore have provided written description.

In order to provide an adequate written description, the specification must reasonably convey to the artisan that the inventor had possession at that time of the claimed subject matter. While a patent applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991) (citing In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)). “The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention.” Kennecott Corp. v. Kyocera

Int'l, Inc., 835 F.2d 1419, 1421, 5 U.S.P.Q.2d 1194, 1197 (Fed. Cir. 1987), cert. denied, 486 U.S. 1008 (1988).

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under §112.

### **Conclusion**

It is believed that the claims now pending are in condition for allowance. Early and favorable action by the Examiner is earnestly requested.

### **Authorization**

No fee is believed to be due. However, the Commissioner is hereby authorized to charge any fees which may be required for consideration of this Amendment to deposit account 13-2755.

Respectfully submitted,

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